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Page 1 of 71 Page ID

1 TABLE OF CONTENTS 2 I. 3 II. PARTIES.....1 4 Α. 5 B. Defendants. 2 6 7 III. 8 FACTUAL ALLEGATIONS.....4 IV. 9 The diabetes care market is enormous......5 A. 10 В. 11 Manufacturing of Incretin Mimetics in the United States.....8 C. 12 D. 13 14 E. 15 F. The rise of the Pharmacy Benefit Managers in the 16 The Role of Pharmacy Benefit Managers in the Incretin 17 G. 18 The Pricing of Victoza, an Incretin Mimetic Produced by Novo H. 19 20 I. 21 V. TOLLING OF THE STATUTE OF LIMITATIONS35 22 Plaintiff and the class are entitled to tolling due to fraud or Α. 23 24 В. 25 CLASS ACTION ALLEGATIONS......37 VI. 26 VII. CLAIMS FOR RELIEF.....42 27 28

| COUNT ONE — VIOLATIONS OF 18 U.S.C. § 1962(C)-(D) THE RACKETEER INFLUENCED AND CORRUPT | 42 |
|--|----|
| ORGANIZATIONS ACT, 18 U.S.C. §1961, ET SEQ | 42 |
| A. Description of the OptumRx RICO Enterprise | 43 |
| B. The OptumRx RICO Enterprise Sought to Fraudulently Increase Defendants' Profits and Revenues | 47 |
| C. Predicate Acts: Mail and Wire Fraud. | 50 |
| COUNT TWO — VIOLATION OF THE CALIFORNIA LEGAL REMEDIES ACT (CAL. CIV. CODE § 1750, ET SEQ.) | 55 |
| COUNT THREE — VIOLATION OF THE CALIFORNIA UNFAIR COMPETITION LAW (CAL. BUS. & PROF. CODE § 17200, ET SEQ.) | 57 |
| COUNT FOUR — VIOLATION OF THE MICHIGAN CONSUMER PROTECTION ACT (MICH. COMP. LAWS § 445.903, ET SEQ.) | 59 |
| COUNT FIVE — VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT (N.J. STAT. ANN. § 56:8-1, ET SEQ.) | 61 |
| COUNT SIX — COMMON LAW FRAUD | 63 |
| COUNT SEVEN — UNJUST ENRICHMENT | 66 |
| VIII. PRAYER FOR RELIEF | 66 |
| IX. JURY DEMAND | 68 |
| | |
| | |
| | |
| | |
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I. INTRODUCTION

- 1. Plaintiff Ruth Johnson, by and through her undersigned attorneys, brings this action individually and on behalf of all others similarly situated against Defendants OptumRx, Inc. ("OptumRx") and Novo Nordisk Inc. ("Novo Nordisk") (collectively, "Defendants") to redress injuries she suffered due to an illegal pricing scheme in which Novo Nordisk, a drug manufacturer, artificially inflated the price of Victoza—an injectable prescription medicine use to treat Type 2 diabetes—to subsidize the payment of illegal kickbacks to OptumRx, a pharmacy benefit manager ("PBM") that negotiates drug prices on behalf of insurers, health plans, and their participants.
- 2. Plaintiff's allegations are based on her own experience and personal knowledge, her research, the research of counsel, publicly available articles, studies, reports, and other sources, a reasonable inquiry under the circumstances, and on information and belief. Plaintiff's allegations are likely to have further evidentiary support after a reasonable opportunity for further investigation and discovery.

II. PARTIES

A. Plaintiff.

3. **Plaintiff Ruth Johnson** is domiciled in the State of Michigan. Ms. Johnson has type 2 diabetes and is insured under a Medicare Part D plan for which Defendant OptumRx administers pharmacy benefits. Among other patient cost-sharing payments that are dependent on the inflated list price of Victoza, Plaintiff Johnson consistently reaches the Medicare Part D "Donut Hole" where she pays a coinsurance of up to \$284.05 for her Victoza medication. For example, as of May 22, 2017, Plaintiff Johnson has already reached the "Donut Hole" and recently purchased Victoza for \$201. On

numerous occasions, Plaintiff Johnson used the prescription drug benefit provided by OptumRx to purchase Victoza, a drug produced by Novo Nordisk to treat her diabetes.

B. **Defendants.**

- 4. **Defendant OptumRx, Inc.** is a corporation organized under the laws of California and headquartered at 2300 Main St., Irvine, California, 92614. OptumRx is a pharmacy benefit manager and, as such, contracts on behalf of health plans, insurers, and the beneficiaries of the health plans for which OptumRx provides pharmacy benefit management services, with Novo Nordisk for purchase of Victoza. As one of the largest pharmacy benefit management companies in the United States, OptumRx covers 65 million lives¹ and reported approximately \$48.2 billion in revenue in 2015 and \$60.44 billion in 2016.²
- 5. **Defendant Novo Nordisk Inc.** ("Novo Nordisk") is a Delaware corporation. Its headquarters are in Plainsboro, New Jersey. Novo Nordisk manufactures diabetes products including Victoza, an incretin mimetic drug. In 2016, Novo Nordisk's revenue for Victoza in the United States was \$2.068 billion.
- 6. Throughout this complaint, when reference is made to a defendant or defendants, this includes the officers, agents, or employees of said defendants as well as predecessor and successor entities to the named defendants.

¹ Ed Kaplan & Wendy Pongracz, *Negotiating and Drafting Pharmacy Benefit Manager Contracts for Self-Insured Plans*, STRAFFORD (June 21, 2016), http://media.straffordpub.com/products/negotiating-and-drafting-pharmacy-benefit-manager-contracts-for-self-funded-plans-2016-06-21/presentation.pdf.

7. **Subject Matter Jurisdiction**. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims arise under federal law, and under 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962. This Court also has supplemental jurisdiction over the state law claims in this action pursuant to 28 U.S.C. § 1367. This Court also has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), (5), because Plaintiff and most members of the putative Class are citizens of different states than the Defendants, the aggregate amount in controversy exceeds five million dollars, exclusive of interest and costs, and the Class has more than 100 members.

- 8. **Personal Jurisdiction**. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district. This Court also has personal jurisdiction over all Defendants pursuant to Fed. R. Civ. P. 4(k)(1)(A) because they would be subject to the jurisdiction of a court of general jurisdiction in California. Further, Defendant OptumRx is headquartered in this district.
- 9. **Venue**. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c), because each Defendant transacts business in, is found in, and/or has agents in this district, and because some of the actions giving rise to the complaint took

place within this district. Venue is also proper in this District pursuant to 18 U.S.C. § 1965, because most Defendants reside, are found, have an agent, or transact their affairs in this District, and the ends of justice require that any Defendant residing elsewhere be brought before this Court. Further, Defendant OptumRx is headquartered in this district.

IV. FACTUAL ALLEGATIONS

- 10. Diabetes is an epidemic in the United States. One in five health care dollars is spent caring for people with the condition.³ In total, nearly 30 million people, 9.3% of the country, live with diabetes.⁴ Failure to properly control blood sugar levels can have severe consequences for diabetes patients, including damage to internal organs, nerves, eyes, feet, and skin.⁵ "Diabetes is the leading cause of kidney failure, adult-onset blindness, and lower-limb amputations" in this country.⁶ Though treatable, diabetes can be severely debilitating or fatal if left untreated. Diabetes-related complications are the "seventh leading cause of death in the United States."
- 11. The most common types of diabetes in the U.S. are type 1 and type 2, as well as gestational diabetes.⁸ Patients with type 1 diabetes are unable to produce insulin at all because their immune system attacks and destroys the cells in the pancreas that

³ American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2012*, 36 DIABETES CARE 1033, 1033 (2013), http://care.diabetesjournals.org/content/36/4/1033.full-text.pdf.

⁴ National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, CENTERS FOR DISEASE CONTROL AND PREVENTION [hereinafter CDC], (2014), https://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf.

⁵ Chronic Disease Prevention and Health Promotion: Diabetes, CENTERS FOR DISEASE CONTROL PREVENTION (July 25, 2016), https://www.cdc.gov/chronicdisease/resources/publications/aag/diabetes.htm.

⁶ *Id*.

 $^{^{7}}$ Id. 8 What is Diabetes?, NATIONAL INSTITUTE OF HEALTH (Nov. 2016),

make it.⁹ Although people with type 2 diabetes are able to produce insulin, they are unable to use it effectively.¹⁰ About 95 percent of cases of diabetes in adults are type 2.¹¹

12. Type 2 diabetes, or adult-onset diabetes, affects approximately 28.5 million people in the United States. Over 37% of US adults 20 years or older (or 86 million Americans) are currently classified as having prediabetes, which places them at greater risk for developing type 2 diabetes.¹²

A. The diabetes care market is enormous.

13. Nearly 116 million Americans have either diabetes or prediabetes.¹³ The condition is a significant source of health care costs. The Center for Disease Control estimates that the total cost of diabetes in the United States in 2012 was 245 billion dollars, 176 billion dollars of which were direct medical costs.¹⁴ "[A]verage medical expenditures among people with diagnoses diabetes were 2.3 times higher than people without diabetes" in 2012.¹⁵ As this complaint demonstrates, these disproportionate costs imposed on people with diabetes are due in large part to the profiteering and deceptive and otherwise unlawful practices of both Pharmacy Benefit Managers and drug manufacturers.

⁹ *Id*.

¹⁰ *Diabetes*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/media/presskits/aahd/diabetes.pdf (last visited May 22, 2017).

¹¹ *Id*.

¹² CDC, *supra* note 4, at 3.

¹³ *See id*.

¹⁴ *Id*. at 8.

¹⁵ *Id*.

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The Staggering Costs of Diabetes

GROWING EPIDEMIC Diabetes affects 29 million children and adults in the U.S. 86 million Americans **Every 23 seconds** have prediabetes and are at risk That's for developing type 2 diabetes someone in the 1 in 11 U.S. is diagnosed 90% of them don't know Americans. they have it. with diabetes. **HUMAN COSTS** African Americans and People with diabetes are at higher risk of serious health complications: Hispanics are almost as likely to have diabetes as non-Hispanic whites. BLINDNESS HEART **ECONOMIC COSTS** People with diabetes have health care costs The total cost of diabetes The average price of and prediabetes in the U.S. is 2.3x greater insulin increased nearly \$322 billion. between 2002 and 2013. without diabetes.

14. No optimal medication currently exists for the treatment of Type 2 diabetes, but the American Diabetes Association (ADA) recommends metformin as the preferred initial pharmacologic agent for the treatment of type 2 diabetes.¹⁷ When metformin is unsuccessful, the addition of an incretin-mimicking medication is recommended.¹⁸

¹⁶ The Staggering Costs of Diabetes In America, AMERICAN DIABETES ASSOC., http://main.diabetes.org/dorg/images/infographics/adv-cost-of-diabetes.gif (last visited May 23, 2017).

¹⁷ Jamie M. Terrell, PharmD, and Tibb F. Jacobs, PharmD, BCPS, *Incretin Mimetics: Pros and Cons, and Emerging Agents in Diabetes Treatment*, AJMC.COM (Dec. 14, 2013), http://www.ajmc.com/journals/evidence-based-diabetes-management/2013/nov-dec-2013/incretin-mimetics-pros-and-cons-and-emerging-agents-in-diabetes-treatment.

¹⁸ *Id*.

15. This case concerns the excessive price of the incretin-mimicking medication Victoza. But to understand incretin-mimicking medicate and the market it is sold in, it is important to first understand what incretins are.

B. What are Incretins and Incretin Mimetics?

- 16. Incretins are hormones made by specialized cells in the small intestine, which release incretin into the body when they sense food passing through the intestines.¹⁹ Incretins then enter the bloodstream and travel around the body, affecting several organs, most importantly the pancreas.²⁰ Incretins spur the pancreas to make insulin, which controls blood glucose levels and brings levels back down after eating.²¹
- 17. Incretins also suppress the production of glucagon, which signals the liver to release its glucose stored into the blood.²² According to Carol Wysham, MD, clinical associate professor of medicine at the University of Washington School of Medicine, the glucagon suppressive effect "may account for 50 percent of the incretin effect."²³
- 18. One of the most important types of incretins hormones—GLP-1 hormones—is responsible for this glucagon suppressive effective. People with type 2 diabetes have depressed GLP-1 levels, which contributes to the impact of diabetes.²⁴
- 19. Merely providing people with type-2 diabetes with additional GLP-1 hormones in a manner similar to insulin injections, however, would be a poor treatment because GLP-1 is quickly broken down by the body through an enzyme called DPP-4.²⁵

¹⁹ Erika Gebel, PhD, *Medications: Incretin Mimetics*, DIABETES FORECAST (June 2012), http://www.diabetesforecast.org/2012/jun/medications-incretin-mimetics.html.

²⁰ *Id*.

²¹ *Id*.

²² *Id*.

Id.24 *Id*.

²⁵ *Id*.

20. As such, the suppressive effect of GLP-1 was not effectively captured as a diabetes treatment until researchers discovered exenatide —a protein in the saliva of the Gila monster, a Southwestern lizard—that is similar to GLP-1, but is not broken down by DPP-4.²⁶

C. Manufacturing of Incretin Mimetics in the United States.

21. Protein engineers were able to synthetically produce the 'incretin-like' protein, which is now sold under the brand name Byetta®, as early as 2005 and soon after, as indicated in the below chart, variations on the protein were developed and produced by a number of manufacturers.²⁷

Figure 2: Quick Guide to Incretin Mimetics²⁸

Quick Guide: Incretin Mimetics

| Medication | Brand (Maker) | Date Approved by FDA | Average Weight Loss (in 6 months) | Average A1C Reduction (percentage points, 6 months) | Dosing |
|------------------------------|------------------------------|----------------------------|---|---|------------------------------------|
| Exenatide | Byetta (Amylin) | April 2005 | 6 lbs. | 0.8 | Twice daily, before meals |
| Liraglutide | Victoza (Novo Nordisk) | January 2010 | 7 to 8 lbs. | 1.1 to 1.5 | Daily |
| Long- acting exenatide | Bydureon (Amylin) | January 2012 | 6 lbs. | 1.3 | Once weekly |

²⁶ *Id*.

²⁷ *Id*.

²⁸ *Id*.

- 22. Liraglutide (Victoza®), the second GLP-1 receptor agonist introduced in the United States market, received its initial FDA approval in 2010 as an adjunct to diet and exercise in patients with type 2 diabetes.²⁹
- 23. In 2012, exenatide long-acting release (Bydureon®) entered the United States market as "the first once-weekly GLP-1 receptor agonist to receive FDA-approved labeling as adjunctive therapy to diet and exercise for patients with type 2 diabetes."³⁰
- 24. "In 2014, the second once-weekly GLP-1 receptor agonist, albiglutide (Tanzeum®), received FDA approval for the treatment of type 2 diabetes in patients unable to achieve glycemic targets."³¹
- 25. As indicated above, incretin mimetics differ in how often they're taken: Exenatide needs to be injected twice a day, in the hour before a meal. Liraglutide is taken once daily, at any time and independent of meals. Long-acting exenatide is a week's worth of regular exenatide that is designed to release gradually. It is injected every seven days, at any time of day, with or without meals.³²
- 26. Regardless of how they are taken, however, these incretin mimetics have been shown to be clinically effective in "the treatment of diabetes, with benefits extending outside glucose control, including positive effects on weight, blood pressure, cholesterol levels, and beta-cell function."³³

²⁹ Lalita Prasad-Reddy and Diana Isaacs, *A clinical review of GLP-1 receptor agonists: efficacy and safety in diabetes and beyond*, DRUGS CONTEXT (Jul. 9, 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4509428/.

Id.31 *Id*.

³² Gebel, *supra* note 19.

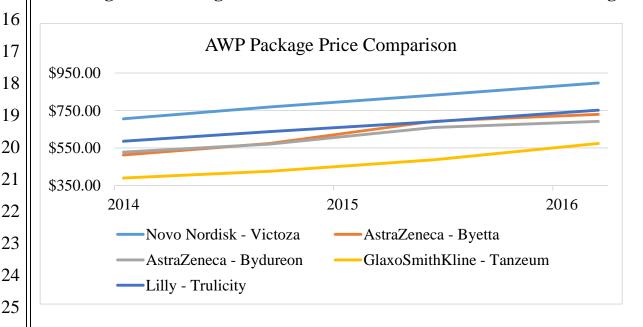
³³ Lalita Prasad-Reddy and Diana Isaacs, *A clinical review of GLP-1 receptor agonists: efficacy and safety in diabetes and beyond*, DRUGS CONTEXT (Jul. 9, 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4509428/.

D. The Pricing of Incretin Mimetics in the United States.

27. Despite their effectiveness, according to Carol Wysham, the biggest drawback of incretin mimetics is their cost. The prices range from around \$300 a month for exenatide to over \$400 a month for liraglutide and are "extraordinarily hard to swallow," says Wysham.³⁴ Insurers may also not cover these medications as well as they cover other diabetes medications.³⁵ "The major barrier from my perspective is that my patients are willing, but insurers are not," says Wysham.³⁶

28. Since the date of Dr. Wysham's criticism, however, the prices for incretin mimetics have only gone up. As indicated in the below chart, prices for these drugs have ballooned to nearly \$900, and this is in the face of additional competing products in the market (such as Eli Lilly's Trulicity-brand GLP-1), which should produce lower, not higher, prices.





³⁴ Gebel, *supra* note 19.

³⁵ *Id*.

³⁶ *Id*.

29. This confounding result of increased competition in the incretin-mimetics market can be explained only by an understanding of the role that Pharmacy Benefit Managers, like OptumRx, play in the pharmaceutical supply chain.

E. The prescription medical product supply chain.

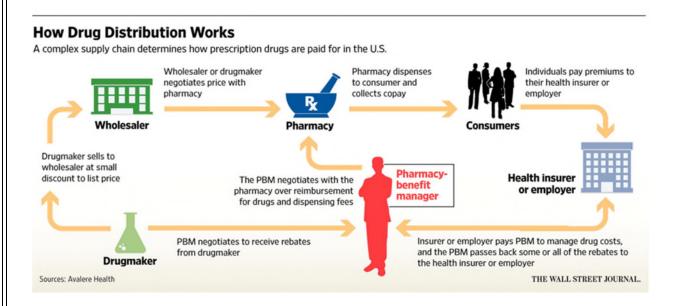
- 30. The supply chain for prescribed medical products in the United States consists of four major actors: Manufacturers, Wholesale Distributors, Pharmacies, and Pharmacy Benefit Managers (PBMs).
- 31. Prescription medical products "originate in manufacturing sites; are transferred to wholesale distributors; are stocked at retail, mail-order, and other types of pharmacies; are subject to price negotiations and processed through quality and utilization management screens by PBMs; are dispensed by pharmacies; and ultimately are delivered to and taken by patients."³⁷
- 32. The technical function of a PBM is to administer a health coverage provider's prescription benefit program. A PBM develops the coverage provider's formulary (the list of prescription benefits included in coverage at various pricing "tiers"), processes claims, creates a network of retail pharmacies that provide discounts in exchange for access to a provider's plan participants, and negotiates with manufacturers. Formularies include prescription drugs, such as incretin mimetic drugs.
- 33. Often, PBMs are also responsible for performing drug utilization reviews and operating their own mail-order, specialty, and retail pharmacies. PBMs also contract with a network of retail and community pharmacies. Pharmacies agree to dispense

³⁷ Health Strategies Consultancy LLC, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, THE KAISER FAMILY FOUNDATION (Mar. 2005), https://kaiserfamilyfoundation.files.wordpress.com/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf.

prescription products to covered patients. The contract provides for a payment rate for each prescription, plus a dispensing fee. Pharmacies are also responsible for collecting patient cost-sharing payments and sending those to the PBM or reducing the PBM's or plan's share owed by that amount.

- 34. In addition, and of particular significance here, PBMs have contractual relationships with medical product manufacturers. PBMs negotiate rebates, fees, and other concessions with the manufacturers. These relationships allow PBMs to exert tremendous influence and control over what products are made available to health plans and insureds.
- 35. The following chart illustrates the prescription supply chain, and the PBMs central role in it:

Figure 4: Prescription Distribution Chain³⁸



³⁸ Joseph Walker, *Drugmakers Point Finger at Middlemen for Rising Drug Prices*, WALL ST. J. (Oct. 3, 2016, 12:43 PM), https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336.

F. The rise of the Pharmacy Benefit Managers in the pharmaceutical supply chain.

- 36. When they first came into existence in the late 1960s, PBMs provided administrative services to health plans by processing claims and maintaining formularies. Over time, they played a larger role negotiating prices with manufacturers of prescription products. Since PBMs were independent, they generally were thought to pass savings back to health plans and consumers by using their leverage to negotiate lower reimbursement rates with pharmacies and discounts with manufacturers.³⁹
- 37. In the 1990s, manufacturers began acquiring PBMs, which caused an "egregious conflict[] of interest," prompting the Federal Trade Commission to undo those deals.⁴⁰ The deals allowed prescription product manufacturers to coordinate pricing policies, see their competitors' sensitive pricing information, and favor their own products over those of their competitors.⁴¹
- 38. In the early and late 2000s, PBMs started buying pharmacies, which has caused a similar conflict of interest that resulted from the merger of manufacturers and PBMs in the 1990s. When a PBM combines with a pharmacy, they "lose the incentive to police against pharmaceutical company schemes to steer patients to more expensive drugs. Indeed, they may collude in them." The power of the largest PBMs has continued to grow, and has allowed them to distort the pharmaceutical supply chain to their own financial advantage.

³⁹ Brian Feldman, *Big pharmacies are dismantling the industry that keeps US drug costs even sort-of under control*, QUARTZ (Mar. 17, 2016), https://qz.com/636823/big-pharmacies-are-dismantling-the-industry-that-keeps-us-drug-costs-even-sort-of-under-control/.

 $^{^{40}}$ *Id*.

⁴¹ *Id*.

⁴² *Id*.

- 39. Manufacturers well understand the power of PBMs.⁴³ Because of their size, and the many thousands of health plan clients they represent, PBMs can steer business from one manufacturer to another based on which one pays the larger PBM Kickback.
- 40. PBMs make outsize profits by exploiting the United States' complex prescription distribution system. While the role of PBMs in the supply chain is well known, the size of the rebates and other fees they extract from companies for formulary placement, and the portion of these payments they pocket (the "PBM Kickbacks") are carefully guarded secrets.⁴⁴
- 41. PBMs depend on the lack of transparency to conduct their business and have vigorously resisted any requirement that they disclose the details of their agreements with manufacturers, and the PBM Kickbacks they receive from manufacturers—as well as their agreements with the insurers and pharmacies.⁴⁵
- 42. Although consumers are led to believe that the list price is the actual price for a prescribed product, the list price is inflated to account for PBM Kickbacks, which are "rebated" back to the PBMs, as shown in the following diagram. Note that the diagram is only illustrative and that insurers do not necessarily receive a large proportion of the "rebates" back from PBMs, which may keep all or most of the PBM Kickbacks in

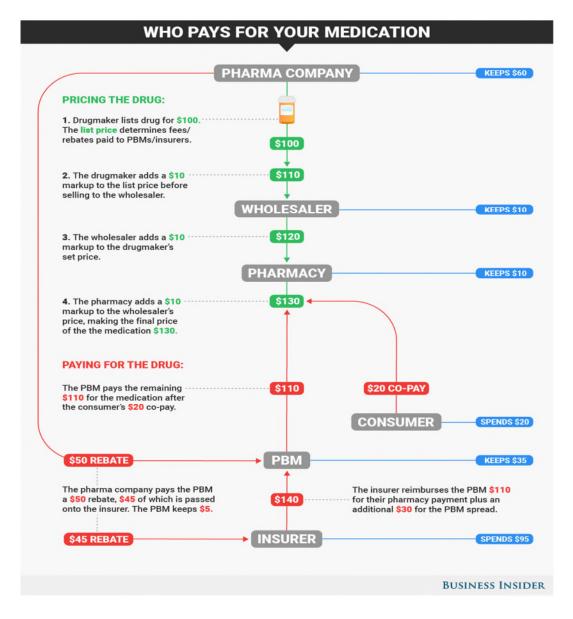
⁴⁵ *Id*.

⁴³ Denise Roland & Peter Loftus, *Insulin Prices Soar While Drugmakers' Share Stays Flat*, WALL St. J., (Oct. 7, 2016, 5:46 PM), https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764.

⁴⁴ See, e.g., Lydia Ramsey, One of the largest middlemen in the drug industry just released a video showing why it should be able to remain secretive, BUSINESS INSIDER (Feb. 9, 2017), http://www.businessinsider.com/what-pharmacy-benefit-managers-are-doing-about-trump-and-drug-pricing-2017-2.

some instances. "Overall, nearly one-third of the total expenditures on branded pharmaceuticals were, in some way, rebated back to PBMs and payers in 2015."

Figure 5: Who Pays for Your Medication⁴⁷



⁴⁶ Wayne Winegarden, *The Economic Costs of Pharmacy Benefit Managers: A Review of the Literature*, Pacific Research Institute (May 2017), at 5.

⁴⁷ Lydia Ramsey and Skye Gould, *A huge pharma middleman just lost its biggest customer* — *and it shows how drug pricing really works*, BUSINESS INSIDER (Apr. 25, 2017, 6:57 AM), http://www.businessinsider.com/express-scripts-esrx-anthem-not-renewing-pbm-2017-4.

G. The Role of Pharmacy Benefit Managers in the Incretin Mimetics Market.

- 43. PBMs serve as both middlemen and gatekeepers between drug and medical supply manufacturers on the one hand, and health insurers and patients on the other. For the PBMs, business is booming. Combined, the three largest PBMs in the United States—OptumRx, ExpressScripts, and CVS Caremark—report more than \$200 billion a year in revenue.⁴⁸ They control close to 80% of the industry, administering and managing pharmacy benefits for over 180 million insureds.⁴⁹
- 44. PBMs are supposed to negotiate lower prices for their clients, health insurers and plan administrators. Using the sheer volume of their clients as leverage, PBMs like Defendant OptumRx set up exclusionary tiered formularies—ranked lists of drugs, such as incretin memetics, where some cheaper and more effective products are supposed to be placed into lower tiers, generally with lower cost-sharing amounts due from patients.
- 45. As indicated in the below chart, different mimetics have been included or excluded from the various PBMs' formularies at different times:

| Caremark/CVS | | | | | |
|---------------------|-----------------|------------|------------|------------|------------|
| Incretin Memetic | Manufacturer | 2017 | 2016 | 2015 | 2014 |
| Victoza | Novo Nordisk | Preferred | Preferred | Preferred | Not Listed |
| Tanzeum | GlaxoSmithKline | Not Listed | Not Listed | Not Listed | Not Listed |
| Bydureon | AstraZeneca | Excluded | Excluded | Preferred | Not Listed |
| Byetta | AstraZeneca | Excluded | Excluded | Excluded | Not Listed |
| Trulicity | Lilly | Preferred | Preferred | Not Listed | Not Listed |

⁴⁸ Kasia Lipska, *Break Up the Insulin Racket*, N.Y. TIMES (Feb. 20, 2016), https://www.nytimes.com/2016/02/21/opinion/sunday/break-up-the-insulin-racket.html. ⁴⁹ *Id*.

Manufacturer

Novo Nordisk

AstraZeneca

AstraZeneca

Lilly

OptumRx

2016

Preferred

Preferred

Preferred

Preferred

2015

Tier 3

Preferred

Preferred

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2014

Tier 3

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Incretin

Memetics Drug

Victoza

Bydureon

Byetta

Trulicity

| Tanzeum | GlaxoSmithKline | Excluded | Not listed | Not listed | Not listed |
|---------------------------|-------------------|--------------|------------|---------------|---------------|
| Bydureon | AstraZeneca | Preferred | Preferred | Not listed | Not listed |
| Byetta | AstraZeneca | Preferred | Preferred | Tier 2 | Tier 2 |
| Trulicity | Lilly | Preferred | Not listed | Not listed | Not listed |
| | | • | | | • |
| | | | | | |
| | F | Express Scri | pts | | |
| Incretin Memetics Drug | H Manufacturer | Express Scri | pts 2016 | 2015 | 2014 |
| | | _ | <u>*</u> | 2015 Excluded | 2014 Excluded |

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- 46. Plan administrators and health insurers rely on PBMs' formularies to calculate how much of their insureds' costs for formulary products they will cover. Medical products that are in the lower, preferred, formulary tiers should be cheaper for health plan members.
- 47. If two medical products are basically interchangeable, a PBM sometimes will exclude from its formulary the more expensive version—again, supposedly based on the price of the product for consumers.
- 48. Health plans that use a PBM's formulary either will not reimburse members for the purchase price of products that are excluded from the formulary or will require members to pay a larger coinsurance amount based on the list price rather than the actual

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26 27 28 net price that the PBM paid. Thus, exclusionary formularies allow PBMs, including OptumRx, to push patients toward certain brands over others. This gives the PBM enormous control over purchasing and leverage over manufacturers.

- 49. While PBMs could use this market power to drive down the prices for medical products by forcing manufacturers to compete on price for formulary placement, instead they and the manufacturers of incretin mimetics—such as Novo Nordisk—have figured out a way to game the system for their mutual benefit. To gain formulary access, the manufacturers have inflated their list prices and then "rebate" a significant portion of the list price back to PBMs, such as OptumRx. The rebates are provided under a variety of labels—discounts, credits, concession fees, etc.⁵⁰ Regardless of the term used to describe them, they are a *quid pro quo* for formulary inclusion or preferential placement.
- 50. The result of this rebating scheme is a vast difference between the list price reported by manufacturers and the net price obtained by the manufacturers after PBMs have taken their rebates.
- 51. PBMs may pass a portion of the rebates to their major insurer clients, some of which are owned by or affiliated with them, and pocket the rest. The higher the rebate, the more the PBMs can pocket. The total amount and nature of the rebates, the amount that the PBM pockets, and the amount that passes through to payers are concealed from insureds and the public.
- 52. This rebate scheme creates the best of both worlds for the Defendants, at the expense of consumers like Plaintiff Johnson. Defendant OptumRx obtains large rebates in

⁵⁰ See, e.g., Linda Cahn, Don't Get Trapped By PBMs' Rebate Labeling Games, Managed Care (Jan. 2009), https://www.managedcaremag.com/archives/2009/1/don-tget-trapped-pbms-rebate-labeling-games.

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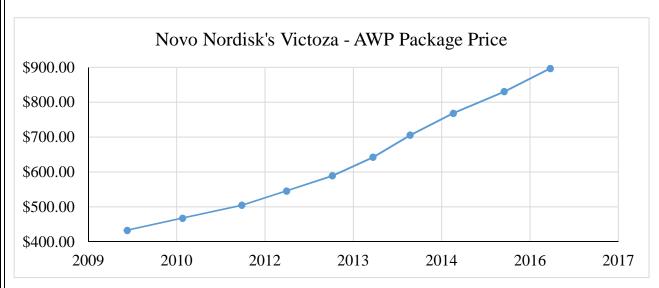
exchange for granting access to the exclusionary formularies, increasing the PBM take, and Defendant Novo Nordisk pays rebates without diminishing its profits because its net profits are protected by the ever increasing list prices, and it is ensured sales through formulary placement.

- 53. The result of this scheme is a wide gap between the price paid by PBMs for incretin mimetics (*i.e.*, the net realized price actually received by the manufacturer), and the publicly available manufacturer list price that affects consumers.
- 54. This scheme has allowed the manufacturers to do something that would be impossible for a product that is subject to normal market conditions: even though multiple manufacturers produce incretin mimetics, certain manufacturers have maintained dominance of the incretin mimetics market while *increasing* prices.

H. The Pricing of Victoza, an Incretin Mimetic Produced by Novo Nordisk.

55. For example, as indicated the below chart, Novo Nordisk raised the average wholesale price of Victoza from \$546.01 in July 2012 to \$589.68.45 the next year, and to \$897.16 in 2016. Since 2009, the price has doubled.

Figure 6: Average Whole Sale Price of Victoza from 2009-2017



56. Novo Nordisk makes no secret of its efforts to increase profits by inflating the price of its medications, as indicated in this exchange between Lars Rebien Sørensen, a Novo Nordisk representative, and Peter Verdult of Morgan Stanley on Novo Nordisk's 2012 investor call:

<u>Peter Verdult</u>: Peter Verdult here for Morgan Stanley. . . . A quick add-on there is just U.S. pricing trends across the insulin portfolio for the industry continues to the price on the upside, just wondering what your thoughts are there. You've been pretty relaxed about the ability to put pricing through in the U.S. I'm wondering if that has -- that you become more confident, or has anything changed as you get the crystal ball out and look out a few years?

Lars Rebien Sørensen: And on the U.S., of course, it is interestingly ironic enough that nothing is disappointing that is not good for something, and the fact that we are now having to plan with a launch of degludec or Tresiba in the beginning of '13 means that we have full marketing power on Victoza and on modern insulins. And they are actually the product that are driving the predominant part of the growth in the first half. And so this will strengthen our case and situation in the U.S. where we have a good momentum behind our insulin business. With regards to pricing, yes, it is perhaps surprising that it is — we've been able to follow the competition in terms of increasing prices in general on insulin products to the tune of some 6%, 8%, 9%, in that order of magnitude. You've got to bear in mind though, that these are list price adjustments and they are often associated with very

significant repays, but the flow-through on our net sales is much, much less than the increases that you hear and refer. In terms of going forward, I think our picture is still the same, that we would be expecting that we'd see relatively modest price increases going forward. So -- but it's all determined by the competitive situation. And so far, it is predominantly been: Leary [ph] and ourselves that determine the price list of insulins in the U.S., with, of course, Sanofi driving the basal price level, given they're the leaders in this segment in the U.S. But there's still caution about the outlook going forward.⁵¹

- 57. Despite Defendants' price increases, "Victoza sales continues to be largely unaffected by the launch of competitors' products. Victoza is gradually increasing its market share and now account for approximately 62% of GLP-1 market by value in the United States," producing more than \$622.33 in revenue for Novo Nordisk in 2017 alone. ⁵³
- 58. The average wholesale prices for incretin mimetics made by other manufacturers has steadily increased as well. Consider, for example, the yearly price increases for the Byetta 5 MCG Pen:

⁵¹ Novo Nordisk A/S Management Discusses Q2 2012 Results - Earnings Call Transcript, SEEKING ALPHA (Aug. 9, 2012; 7:00 AM), https://seekingalpha.com/article/800111-novo-nordisk-a-s-management-discusses-q2-2012-results-earnings-call-transcript.

⁵² Novo Nordisk's CEO Discusses Q4 2012 Results - Earnings Call Transcript, Seeking Alpha (Jan. 31, 2013, 8:30 AM), https://seekingalpha.com/article/1148641-novo-nordisks-ceo-discusses-q4-2012-results-earnings-call-transcript.

⁵³ *Q1 Financial Data*, Novo Nordisk, (2017), http://www.novonordisk.com/content/dam/Denmark/HQ/investors/irmaterial/downloada ble_financial_data/2017/20170503_Downloadable%20financial%20data.xlsx.

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| Byetta 5 MCG Pen Subcutaneous Solution Pen injector 5 MCC/0 02MI | | | | | |
|--|---------------------------|--|--|--|--|
| · · · | Pen-injector 5 MCG/0.02ML | | | | |
| Effective Date | AWP Package Price | | | | |
| 1/1/2017 | \$801.94 | | | | |
| 7/1/2016 | \$729.04 | | | | |
| 1/1/2016 | \$694.32 | | | | |
| 7/1/2015 | \$619.93 | | | | |
| 1/1/2015 | \$574.01 | | | | |
| 12/11/2014 | \$512.51 | | | | |
| 7/1/2014 | \$512.51 | | | | |
| 1/1/2014 | \$474.54 | | | | |
| 4/1/2013 | \$423.70 | | | | |
| 7/26/2012 | \$378.30 | | | | |
| 10/20/2011 | \$350.28 | | | | |
| 5/12/2011 | \$333.72 | | | | |
| 11/4/2010 | \$298.08 | | | | |
| 2/25/2010 | \$265.93 | | | | |
| 9/26/2009 | \$246.23 | | | | |
| 4/3/2009 | \$256.49 | | | | |
| 10/10/2008 | \$240.84 | | | | |
| 1/11/2008 | \$223.00 | | | | |
| 2/2/2007 | \$210.38 | | | | |
| 3/9/2006 | \$194.78 | | | | |
| 5/23/2005 | \$183.75 | | | | |

- 59. Nevertheless, OptumRx—which is supposed to negotiate *lower* prices for medical products—lists these two incretin mimetics (Victoza and Byetta) as the preferred or even exclusive brands on its formularies because this scheme generates profits for OptumRx without actually requiring manufactures to lower their prices.
- 60. In contrast, products that have been excluded from preferential formulary treatment by OptumRx and other PBMs, such as Tanzeum, have been offered on the market for consistently lower list prices, as indicated in the below chart:

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| Effective Date | Tanzeum AWP Package Price |
|----------------|---------------------------|
| 4/1/2017 | \$626.41 |
| 10/1/2016 | \$574.69 |
| 1/1/2016 | \$527.24 |
| 9/29/2015 | \$488.18 |
| 4/14/2015 | \$426.36 |
| 6/30/2014 | \$391.15 |

61. OptumRx and other PBMs tout their market power and ability to drive down prices for prescription products. They boast about the "rebates" or "discounts" for which they bargain with manufacturers. The story they tell is that these rebates and discounts are obtained for the benefit of patients since they purportedly result in lower costs for prescription products. In their latest Form 10-K filed with the United States Securities Exchange Commission, Defendant OptumRx reported that its PBM business helped "improve overall health system performance through optimizing care quality, reducing costs and improving consumer experience. . . ."⁵⁴

- 62. OptumRx also claims that its PBM "businesses have dedicated units that help improve overall health system performance through optimizing care quality, reducing costs and improving consumer experience and care provider performance leveraging distinctive capabilities in data and analytics, pharmacy care services, population health, health care delivery and health care operations."⁵⁵
- 63. But the story that OptumRx and other PBMs tell is far from the whole truth. They obtain rebates and discounts, but neglect to reveal the large portion of the rebates that they pocket. They also neglect to reveal that their formulary decisions are based on the amount of the spread they obtain from the rebate paid by manufacturers. And they

⁵⁴ UnitedHealth Group, *supra* note 2.

⁵⁵ *Id*.

56 See Roland, supra note 43.57 See id.

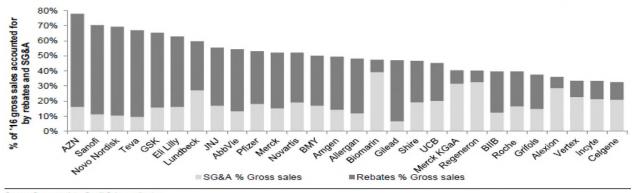
neglect to reveal that the consequence of this scheme is higher costs for patients, whose payments at the pharmacy point of sale are calculated based on the unrebated list price of medical products, not the lower price paid by the PBMs after all rebates and other financial benefits received by the PBMs from the manufacturers and other third parties are taken into account. ⁵⁶ Indeed, PBMs, such as OptumRx, misrepresent the role they play in the supply chain, and their impact on the prices actually paid by consumers. PBMs are avaricious middlemen, with a stranglehold on the medical supply chain. Their scheme to sell formulary access for rebates drives up the cost of prescription drugs and other medical products for the people who need to use them to stay alive.

64. Manufacturers, such as Novo Nordisk, are equally at fault. Their conduct deprives patients of a fair price for incretin mimetics, like Victoza—a price that would result from the operation of normal market forces. They maintain the ability to sell mimetics to the millions of Americans who depend on them, without having to lower the "real," net prices to gain market share. They bargain for market share by providing everlarger rebates to PBMs and entering into exclusive relationships with those PBMs, inflating the prices paid by consumers in order to preserve their net realized price.⁵⁷ Their refusal to disclose their net realized prices for their incretin mimetic drugs and the web of confidentiality agreements they have created and/or participated in with PBMs have been critical to the furtherance of this scheme.

65. Defendant Novo Nordisk is among the worst offenders. According to the report by Credit Suisse reproduced below, more than 90% of Novo Nordisk's promotional spend is on rebates:

Figure 7: Credit Suisse Graph on Percentage of Rebates in US⁵⁸

Figure 7: Full promotion spend: SG&A & rebates as a % of US gross drug sales per company in 2016



Source: Company data, Credit Suisse estimates

66. In fact, Novo Nordisk has openly admitted to "competing" with other manufacturers through offering rebates, as this exchange between Jesper Brandgaard, a Novo Nordisk representative, and Richard Vosser, of JP Morgan Chase & Co, on a 2013 investor call, indicates:

Richard Vosser: Two questions on Victoza, please. I think yesterday, you mentioned there's a potential slowdown or some slowdown in GLP-1. Just wondering whether there's any patients moving off GLP-1 as they come to - come out of control, whether there's anything do with that here. And whether you have an idea of how long patients are staying in control on Victoza now, it's been on the market for a while? And then, also on the Express Scripts stuff, you mentioned a negative 1% hit in your guidance

⁵⁸ Credit Suisse, *Global Pharma and BioTech Sector Review*, 6 (Apr. 18, 2017).

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from that in the contract loss in 2014. I'm just wondering what you're allowing for Victoza in terms of the losses in patients there, whether you're factoring any greater rebates going forward to defend from Bristol and Astra being more aggressive? [...]

Jesper Brandgaard: [...] And then in terms of Express Script, it is correct that we noted as one of the factors behind the high single-digit guidance for local currency sales growth next year, noted that we had a contract loss with Express Scripts for their national formulary, and we don't fully know what the effect is going to be because there are some opportunities for individual health care plans to opt out under that national formulary. But I think the currency ballpark figure we can provide is 1% effect on full year turnover. And at this point in time, I would say it will be roughly equally divided between the Victoza franchise and the NovoLog franchise. And then in terms of, you also ask, have we factored in any particular change in the rebate structure in GLP-1 in the U.S. for 2014 guidance? And I would say no. We are assuming a continuation of the rebates, the rebating that's been done for the last couple of years. I note that we have been offering a slightly higher rebate to higher control plans at the Medicare Part B, and that has actually improved – increased the coverage. And I think we are today in the high 80s in terms of having a good formulary access in the U.S. And I think what we've been working hard with has been the Medicare Part D. And I

would assume that, that would continue into next year, but no specific changes to the rebates.⁵⁹

67. What's more, Defendants admit that their sales depend on rebate-driven price increases—which other manufacturers of incretin mimetics also engage in—as Lars Rebien Sørensen, a Novo Nordisk representative explained, on an investor call from the same year:

What has happened is that our competitors have raised the list price. What their net take-home price will be in -- is dependent on which channels they end up serving their products to and hence, which kind of rebate they're offering to these different channels i.e. where the patients come from, that eventually will buy these products. And so -- and typically, of course, the list price increase is higher and then some of this is paid back to the distribution chain in terms of rebate.⁶⁰

I. Consumer costs in the Victoza supply chain.

68. Defendants' scheme to make increasing profits from Victoza has a devastating effect on the lives of real people. Unlike PBMs, insurers, pharmacies, health plans, and patients are directly subjected, by PBMs, to the list price artificially set by manufacturers, such as Novo Nordisk. The Commissioner of the FDA, Dr. Scott Gottlieb, explained how this harms consumers:

⁵⁹ Novo Nordisk A/S Management Discusses Q3 2013 Results - Earnings Call Transcript, SEEKING ALPHA (Nov. 1, 2013, 8:20 AM), https://seekingalpha.com/article/1798732-novo-nordisk-a-s-management-discusses-q3-2013-results-earnings-call-transcript.

⁶⁰ Novo Nordisk A/S Management Discusses Q2 2013 Results - Earnings Call Transcript, SEEKING ALPHA (Aug. 8, 2013, 7:00 AM), https://seekingalpha.com/article/1620302-novo-nordisk-a-s-management-discusses-q2-2013-results-earnings-call-transcript.

[The rebates] don't necessarily help offset the costs paid by those who need a particular drug. . . . [I]f a patient needs a particular drug, they will increasingly find that they are paying the full, negotiated price at the pharmacy counter. They never see the real "net" price, after the rebate is applied much later. The rebate is paid to the health plan, not the patient buying the drug.⁶¹

The manner and extent of this impact depends on how patients get their prescriptions.

- 69. **Uninsured**. First, uninsured consumers—because they are completely outside of the PBMs' and manufacturers' web of PBM Kickback financing arrangements through health plans—must pay the full list price for Victoza. This is not a small population. Although the coverage rates have increased significantly lately, by the end of 2015 there were still 28.5 million nonelderly Americans who lacked insurance. In 2012, there were 2 million adults between the ages of 18-64 with diabetes without health insurance coverage, which has "considerable public health and economic impact."
- 70. **Deductibles**. Second, consumers who are in health plans suffer directly from the inflated Victoza price when they pay their deductibles. The deductible is the amount that an insured must pay before insurance benefits will contribute to medical and pharmacy expenses. Thus, until the deductible is met, an insured must pay out-of-pocket.

⁶¹ Winegarden, *supra* note 46, at 6.

⁶² Key Facts about the Uninsured Population, THE KAISER FAMILY FOUNDATION (Sept. 29, 2016), http://kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/.

⁶³ Sarah Casagrande & Catherine Cowie, *Health Insurance Coverage Among People With and Without Diabetes in the U.S. Adult Population*, DIABETES CARE, Nov. 2012, 35(11), 2243-2249, available at: http://care.diabetesjournals.org/content/35/11/2243.

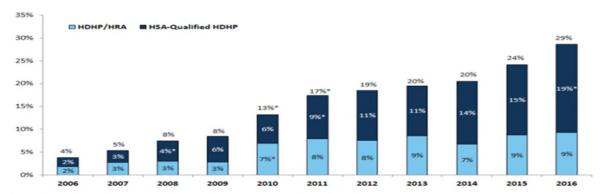
Depending on the plan, consumers may be required to pay the full list price of drugs and other medical needs.

- 71. Moreover, deductibles are rising, meaning that insured consumers are having to pay more out-of-pocket for medical needs, including Victoza. The Kaiser Family Foundation found that in 2016, "deductibles rose 12% in the market group and four times faster than premiums increased." The higher the deductible, the more consumers have to pay full price for their prescriptions until their coverage begins.
- 72. "Almost a quarter of all people obtaining insurance through employers are now enrolled in high-deductible-health plans ("HDHPs"), up from 4% in 2006. The average deductible amount has increased 67% since 2010. And almost half of workers are covered by insurance with annual deductibles of at least \$1,000 for individual coverage." With the surge in popularity of "high-deductible" plans among employer-sponsored health plans, deductible thresholds affect an ever-increasing number of patients:

⁶⁴ Drew Altman, *The Missing Debate Over Rising Health-Care Deductibles*, THE KAISER FAMILY FOUNDATION (Sept. 18, 2016), http://kff.org/health-costs/perspective/the-missing-debate-over-rising-health-care-deductibles/.

⁶⁵ Don't Be Fooled By Eli Lilly's & Express Scripts' New Insulin Program, NATIONAL PRESCRIPTION COVERAGE ASSOCIATION (2017), http://nationalprescriptioncoveragecoalition.com/dont-be-fooled-by-eli-lillys-express-scripts-new-insulin-program/.

Figure 8: Percent Increase of High-Deductible Plans:66



*Estimate is statistically different from estimate for the previous year shown (p < .05).

NOTE: Covered Workers enrolled in an HDHP/SO are enrolled in either an HDHP/HRA or a HSA-Qualified HDHP. For more information, see the Survey Methods Section. The percentages of covered workers enrolled in an HDHP/SO may not equal the sum of HDHP/HRA and HSA-Qualified HDHP enrollment estimates due to rounding.



73. High deductible plans require consumers to pay thousands of dollars before their coverage kicks in. Many individuals and families cannot afford to hit their high-deductible costs year after year. As a result, rising list prices for drugs and other prescription products are particularly harmful to patients in high-deductible plans, not only because they hit their deductibles annually, but because they hit their deductibles over a *shorter period of time*, resulting in significant financial burden at the start of each calendar year.

74. **Cost sharing**. Third, even after deductibles are paid, insured consumers' prescription costs are still affected by the PBMs' and manufacturers' pricing scheme through copayments and coinsurance requirements. Some plans require these payments during the deductible phase, while others require payment of the full list price with copayments and coinsurance requirements only after the deductible is met.

⁶⁶ Employer Health Benefits: 2016 Summary of Findings, THE KAISER FAMILY FOUNDATION (2016),

https://kaiserfamilyfoundation.files.wordpress.com/2016/09/employer-health-benefits-2016-summary-of-findings.pdf.

- 75. Copayments are set amounts that an insured must pay for medical services, including prescriptions. Copayments vary by the prescribed product, with products in preferred formulary positions carrying a lower copay and products in a disfavored position costing the insured more. For example, if Victoza is moved to a less preferred tier on a PBM's formulary, for example, a patient then must spend more because of that less favorable formulary placement, which is driven by Defendants' pricing scheme.
- 76. Coinsurance is a percentage of the cost of a medical service or prescription product that the insured must pay. In the case of prescription products, the coinsurance amount is based on the inflated list price, not an adjusted price based on the secret rebates and kickbacks that PBMs negotiate, and not the amount that manufacturers actually collect or the PBMs actually pay.
- 77. To add insult to injury, the portion of prescription costs that an insured person's plan will pay is often not based on the full, inflated list price—it is based on a negotiated lower price, which will take into account some rebates, discounts, or other concessions passed through to the plan by the PBM. Thus, plans with such arrangements do not simply pay the difference between the participant's payment and the list price—they instead pay something less—and for large insurers or those that own PBMs, something much less. The burden on participants and beneficiaries of such plans is disproportionate to whatever percentages they may think they are shouldering.
- 78. **Medicare**. Fourth, consumers covered by Medicare are also overcharged as a result of the Victoza pricing scheme. In 2017, for many Medicare Part D participants, there is an initial yearly deductible phase during which Medicare Part D plan participants

1 must foot the entire bill for the inflated cost of drugs.⁶⁷ After meeting the deductible, 2 Medicare Part D participants enter the initial coverage phase during which they are 3 responsible for a copay or a 25% coinsurance payment. ⁶⁸ They stay in this phase until 4 5 their payments plus the plan's payments total \$3,700 on covered drugs.⁶⁹ The inflated 6 price increases Medicare Part D participants' costs and also the plan's costs, pushing 7 participants into what is known as the Medicare Part D "Donut Hole," which refers to the 8 coverage gap phase during which participants must pay even more. In 2017, for brand 9 drugs, participants pay 40% 70 of the list price (the manufacturer discounts brand drugs by 10 50%, and the plan pays the remaining 10%).⁷¹ Again, the percentage-of-cost requirement 11 12 means that inflated Victoza prices hurt Medicare participants in this third coverage phase. 13 For 2017, once participants spend \$4,950 total in out-of-pocket costs, they enter the 14 catastrophic phase during which they pay a 5% coinsurance requirement for covered 15 drugs—which is also when total drug costs covered by the participant, the plan, and 16 discounts are estimated to reach \$7,425.72 Medicare Part D participants aren't being 17 denied benefits, but rather, their copays and/or coinsurance payments—and their total 18 19 cost-sharing obligations—are correspondingly increasing with the list price of Victoza.

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⁶⁷ Yearly deductible for drug plans, MEDICARE.GOV, https://www.medicare.gov/part-d/costs/deductible/drug-plan-deductibles.html (last visited May 19, 2017).

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 ⁶⁸ Copayment/coinsurance in drug plans, MEDICARE.GOV, https://www.medicare.gov/part-d/costs/copayment-coinsurance/drug-plan-copayments.html (last visited May 19, 2017).
 ⁶⁹ Costs in the coverage gap, MEDICARE.GOV, https://www.medicare.gov/part-

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d/costs/coverage-gap/part-d-coverage-gap.html (last visited May 19, 2017).

To In prior years in the Class Period, these percentages were even higher—for example Donut Hole cost sharing for participants was 50% in 2011 and 2012.

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⁷¹ Costs in the coverage gap, supra note 68.

⁷² Catastrophic coverage, MEDICARE.GOV, https://www.medicare.gov/part-d/costs/catastrophic-coverage/drug-plan-catastrophic-coverage.html (last visited May 22, 2017).

Standard Medicare Prescription Drug Benefit, 2017



NOTE: Some amounts rounded to nearest dollar. ¹Amount corresponds to the estimated catastrophic coverage limit for non-low-income subsidy (LIS) enrollees (\$7,425 for LIS enrollees), which corresponds to True Out-of-Pocket (TrOOP) spending of \$4,950, the amount used to determine when an enrollee reaches the catastrophic coverage threshold in 2017. SOURCE: Kaiser Family Foundation illustration of standard Medicare drug benefit for 2017.



79. Thus, Medicare Part D participants face a double burden when it comes to inflated drug prices. First, they cost-share based on inflated Victoza list prices, often paying the entire drug cost in their deductible phase, and paying percentages of inflated drug prices in later coverage phases. Second, because the total list price of the drug, including amounts contributed by other parties, is used to calculate when the participant reaches each coverage phase's breakpoints throughout the year, the inflated price of Victoza pushes the participants into the "Donut Hole" faster—where coverage is less

⁷³ The Medicare Part D Prescription Drug Benefit, THE KAISER FAMILY FOUNDATION (Sept. 26, 2016), http://kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/.

generous and their out-of-pocket costs are higher. The acceleration of Medicare Part D participants' movement through coverage phases due to inflated drug prices means they ultimately pay even more for Victoza and other drugs they need.

- 80. People with diabetes who rely on incretin mimetics like Victoza to maintain safe blood glucose levels are the victims of the Defendants' scheme. These patients are burdened with exorbitant out-of-pocket expenses for their treatments because their payment obligations are based on the list prices, not the opaque net prices provided to PBMs. This is so regardless of whether these patients are uninsured and paying the entire list price or whether they are insured and paying large deductibles, coinsurance, or high-tier copayments. All of these patients are making payments based on the inflated list price.
- 81. This lawsuit alleges that Defendants violated the Racketeer Influenced and Corrupt Organizations Act ("RICO"), various state consumer protection laws, and state common law, by engaging in extortion, a RICO enterprise, and deceptive conduct, whose purpose is to unlawfully extract ever-larger portions of rebates along with other payments—"PBM Kickbacks"—from Novo Nordisk, and other incretin mimetics manufacturers.
- 82. Plaintiff further alleges that Novo Nordisk has provided OptumRx with increasingly large rebates and kickbacks by inflating their list prices, and have further conspired to prevent disclosure of net prices to consumers—also in violation of the aforementioned laws. Defendants' scheme directly and foreseeably causes consumers to overpay for these life-saving medications. Thus, this action is brought to redress Plaintiff's injuries that flow from Defendants' scheme—which has driven up the cost of

incretin mimetics—and in particular Victoza—to the substantial benefit of PBMs and the manufacturers of incretin mimetics—and to obtain prospective injunctive relief to curtail Defendants' practices and provide greater transparency in pricing, as well as lower prices going forward. The causes of action asserted herein allow, *inter alia*, the remedies of monetary damages, damage multipliers, restitution, injunctive relief, and other equitable relief.

V. TOLLING OF THE STATUTE OF LIMITATIONS

- A. Plaintiff and the class are entitled to tolling due to fraud or concealment.
- 83. By its nature, Defendants' pricing scheme has hidden Defendants' unlawful conduct from consumers and injured parties. Plaintiff and Class members had no way of knowing about Defendants' pricing scheme and deception with respect to Victoza pricing, nor could they have reasonably discovered its existence until shortly before filing this action.
- 84. Through the exercise of reasonable diligence, Plaintiff and members of the proposed Class could not have discovered within the time period of applicable statutes of limitation that Defendants were engaged in and/or concealing the conduct described in this Complaint and misrepresenting the true cost of Victoza and the amount of PBM Kickbacks that resulted from the scheme.
- 85. Nor did Plaintiff and other Class members know of facts that would have caused a reasonable person to suspect that Defendants were engaged in the pricing scheme. A reasonable and diligent investigation would not have discovered these facts.
- 86. Even today, lack of transparency in Victoza pricing and the arrangements, relationships, and agreements between and among the manufacturers and PBMs that

result in the PBM Kickbacks continue to hide Defendants' unlawful conduct from members of the Class.

- 87. Thus, the discovery has tolled all applicable statutes of limitation with respect to claims as to Victoza as described in this Complaint.
- 88. Defendants' knowing and active fraudulent concealment and denial of the facts alleged in this Complaint throughout the time period relevant to this action also have tolled all relevant statutes of limitation. While the RICO statute does not contain an express limitation period, the United States Supreme Court has held that civil RICO claims must be brought within four years from the discovery of an injury, which limitation is subject to equitable tolling due to defendants' fraudulent concealment of their unlawful conduct.⁷⁴
- 89. Defendants' scheme—by its nature a secret endeavor by Defendants—remains hidden from most members of the Class. The precise amount of PBM Kickbacks remains information in Defendants' possession and largely a mystery to the Class. Moreover, during the Class Period, as defined below, each Defendant actively and effectively concealed its participation in the scheme from Plaintiff and other members of the Class through opaque practices and secrecy policies. There is no question that Plaintiff's claims are timely.

B. Estoppel.

90. Defendants were under a continuous duty to disclose to Plaintiff and Class members the true price that they should have been charged for Victoza, rather than the artificially inflated list price that resulted from Defendants' Scheme; the net price paid by

⁷⁴ *Rotella v. Wood*, 528 U.S. 549 (2000).

OptumRx for Victoza, the existence of the Defendants' Scheme, and the impact that it had on Plaintiff's and Class members' payment obligations for Victoza. Defendants are estopped from relying on any statutes of limitations in defense of this action.

VI. CLASS ACTION ALLEGATIONS

- 91. Plaintiff repeats and re-alleges every allegation above as if set forth in full herein.
- 92. Pursuant to Federal Rule of Civil Procedure 23(a), (b)(3), (b)(2), and (b)(1), Plaintiff brings this suit on her own behalf and on behalf of the proposed class of other similarly situated persons, consisting of:

All individuals residing in the United States and its territories who purchased Victoza and were required to pay all or a portion of the purchase price.

Plaintiff reserves the right to redefine the Class prior to certification.

- 93. **Class Period**. Plaintiff will seek Class certification, damages, losses, and other available relief for the entire period allowable under RICO, 18 U.S.C. 1961, *et seq*. and the doctrine of equitable tolling, as well as under all state statutory and common law claims at issue here. Further, Plaintiff reserves the right to refine the Class Period after the extent of Defendants' fraud and the length of its concealment is discovered.
 - 94. Excluded from the Class are:
- A. The named Defendants and any entity in which they have a controlling interest, their subsidiaries and affiliates, and their legal representatives, officers, directors, assignees, and successors and;

- B. Any co-conspirators, and their officers, directors, management, employees, subsidiaries, and affiliates.
- 95. People with diabetes and their caregivers must pay a portion of the inflated list price under a number of different guises, including insurance deductibles, coinsurance, fixed copayments that are based on the inflated list price, and, of course, uninsured diabetes patients must pay the entire list price.
- 96. And, for patients who pay any of these types of charges for Victoza, the price that a person pays out-of-pocket for the drug is calculated based on the inflated list price. Therefore, each person who pays such charges meets one of the Class definitions and each incurred damages that are directly related to the inflated list prices driven by Defendants' Scheme.
- 97. This action is brought, and may properly be maintained, as a class action pursuant to Fed. R. Civ. P. 23. This action satisfies the numerosity, typicality, adequacy, predominance, and superiority requirements of those provisions.
- 98. **Numerosity**. Upon information and belief, the Class consists of millions of purchasers residing throughout the United States. Accordingly, it would be impracticable to join all Class Members before the Court. The Class is readily identifiable from information and records in possession of the Defendants.
- 99. **Typicality**. Plaintiff's claims are typical of the members of the Class, in that they share facts and legal claims or questions with Class Members, there is a sufficient relationship between the damage to Plaintiff and Defendants' conduct affecting Class Members, and Plaintiff does not have interests that are adverse to those of other Class Members.

- 100. Adequacy. Plaintiff will fairly and adequately protect the interests of Class Members and has retained competent counsel that have experience prosecuting complex class actions, including complex questions that arise in consumer protection litigation. Counsel have specific experience litigating pharmaceutical class actions and cases involving Pharmacy Benefit Managers.
- 101. **Commonality**. Numerous and substantial questions of law and fact are common to all members of the Class—all of whom were affected by the Defendants' Scheme. Some of the common questions of law and fact are:
 - i. Whether the Defendants artificially inflated the list prices of Victoza;
 - ii. What the actual net prices for Victoza is;
 - iii. Whether the list prices for Victoza are deceptive;
 - iv. Whether members of the Class must pay a portion (or all) of the inflated list prices for Victoza;
 - v. Whether the reason why Novo Nordisk artificially increased the list price for Victoza was to gain better placement on OptumRx's formulary;
 - vi. Whether OptumRx profits from the discrepancy between the net prices and the inflated list prices for Victoza;
 - vii. Whether Defendants' marketing materials and other communications distributed by Defendants were false or misleading;
 - viii. Whether Defendants omitted material facts or disclosures;

| 1 | ix. | Whether Defendants intended to defraud or harm Plaintiff and |
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| 2 | IX. | |
| 3 | | Class members; |
| 4 | х. | Whether Defendants violated RICO; |
| 5 | xi. | Whether Defendants violated state consumer protection laws; |
| 6 | xii. | Whether Defendants utilized or formed enterprises for the purpose |
| 7 | | of carrying out a scheme intended to defraud Plaintiff and the |
| 8 | | Class; |
| 9 | xiii. | Whether Defendants used the U.S. mails and interstate wire |
| 10 | | facilities to carry out a scheme intended to defraud Plaintiff and the |
| 11 12 | | · |
| 13 | | Class; |
| 14 | xiv. | Whether Defendants used the U.S. mails and interstate wire |
| 15 | | facilities to carry out their conspiracy and agreement; |
| 16 | XV. | Whether Defendants are liable to Plaintiff and the Class members |
| 17 | | for damages; |
| 18 | xvi. | Whether Plaintiff and the Class are entitled to compensatory |
| 19 | | damages and, if so, the nature of such damages; |
| 20 | xvii. | Whether Plaintiff and the Class are entitled to exemplary or |
| 21 | | punitive damages and, if so, the nature of such damages; and |
| 22 | xviii. | Whether Plaintiff and the Class are entitled to injunctive or |
| 23 | Aviii. | |
| 24 | | equitable relief and, if so, the nature of that relief. |
| 25 | 102. A class action is superior to other methods for the fair and efficient | |
| 26 | adjudication of this co | ontroversy, since individual joinder of all Class Members is |
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impracticable and no other group method of adjudication of all claims asserted herein is more efficient and manageable for at least the following reasons:

- a. The liability claim presented in this case predominates over any questions of law or fact, if any exists at all, affecting any individual member of the Class;
- b. Absent a Class, the Class Members will continue to suffer damage and Defendants' unlawful conduct will continue without remedy while Defendants profit from and enjoy their ill-gotten gains;
- c. Given the size of individual Class Members' claims, few, if any, Class Members could afford to or would seek legal redress individually for the wrongs Defendants committed against them, and absent Class Members have no substantial interest in individually controlling the prosecution of individual actions;
- d. When the liability of Defendants has been adjudicated, claims of all Class Members can be administered efficiently and/or determined uniformly by the Court; and
- e. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiff and members of the Class can seek redress for the harm caused to them by Defendants.
- 103. This action is also maintainable as a class action under Rule 23(b)(2) because Defendants have acted, or refused to act, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief respecting the Class as a whole.

- 104. With respect to Rule 23(b)(1)(B), the prosecution of separate actions by each plaintiff in the Class would create a risk of adjudications with respect to individual members of the Class which would, as a practical matter, be dispositive of the interests of the other members not parties to the actions, or substantially impair or impede their ability to protect their interests.
- 105. Finally, Class action status is also warranted under Rule 23(b)(1)(A) because prosecution of separate actions by the members of the Class would create a risk of establishing incompatible standards of conduct for Defendants.
- 106. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VII. CLAIMS FOR RELIEF

COUNT ONE — VIOLATIONS OF 18 U.S.C. § 1962(C)-(D) THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. §1961, *ET SEQ.*

(By Plaintiff on Behalf of All Members of the Class, Against Defendants OptumRx and Novo Nordisk)

- 107. Plaintiff incorporates by reference each preceding paragraph as though fully set forth herein.
- 108. Plaintiff brings this Count individually and on behalf of the Class against Defendants OptumRx and Novo Nordisk (inclusively, for purposes of this Count, the "OptumRx RICO Defendants").
- 109. At all relevant times, the OptumRx RICO Defendants have been "persons" under 18 U.S.C. § 1961(3) because they are capable of holding, and do hold, "a legal or beneficial interest in property."

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⁷⁷ 18 U.S.C. § 1961(4).

- 110. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity."⁷⁵
- 111. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions.⁷⁶
- 112. As explained in detail below, the OptumRx RICO Defendants sought to infiltrate the business arrangement established between drug manufacturers, health plans, and insurance companies across the country through a fraudulent scheme designed to secure greater profits and market share, increase the cost of Victoza and other prescription drugs, secure a favorable formulary position for Novo Nordisk's products, and extract millions of dollars of revenue from Plaintiff and the Class. As explained in detail below, the OptumRx RICO Defendants' years-long misconduct violated sections 1962(c) and (d).

Description of the OptumRx RICO Enterprise. Α.

113. RICO defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity."⁷⁷ An association-in-fact enterprise requires three structural features: (1) a purpose; (2) relationships among those associated with the enterprise; and (3) longevity sufficient to permit those associates to pursue the enterprise's purpose.⁷⁸

⁷⁵ 18 U.S.C. § 1962(c). ⁷⁶ See 18 U.S.C. § 1962(d).

⁷⁸ *Boyle v. United States*, 556 U.S. 938, 946 (2009).

- 114. For years, OptumRx and other pharmacy benefits managers played a small but meaningful role in the prescription product and insurance business: providing administrative services on behalf of health plans that offer prescription benefits and negotiating with manufacturers on their behalf.
- 115. In the past decade, however, OptumRx and other PBMs began to exert influence in their role as insurance-industry middle-men to dictate the success or failure of certain drugs and other medical products in the marketplace by offering to include or threatening to exclude certain medications from some or all of their formularies and, in the process, extracting hundreds of millions of dollars in the form of "discounts" or "rebate" payments from manufacturers in exchange.
- 116. Negotiations between PBMs and manufacturers regarding those discounts, however, take place in complex, closed-door meetings, during which PBMs sell access to their formularies in exchange for large rebates or discounts, a substantial portion of which they pocket as pure profit.
- 117. In order to facilitate the payment of 'rebates' to PBMs, and ensure their position on certain formularies without impacting their bottom line, prescription drug manufacturers, including Novo Nordisk, participate in a scheme with OptumRx, and other PBMs, to increase the list price of their medications, including Victoza, instead of competing on cost with other manufacturers.
- 118. This scheme to increase the profits of PBMs through artificially increasing the list price of prescription drugs, including Victoza, benefits everyone in the industry's supply chain except Plaintiff and the Class, who are left paying fraudulently obtained, exorbitant, and ever-increasing prices for their medication.

- 119. At all relevant times, the OptumRx RICO Defendants, along with insurance companies, pharmacies, wholesalers, and other individuals and entities, including unknown third parties, operated an ongoing association-in-fact enterprise. This association-in-fact enterprise was formed for the purpose of ensuring that Novo Nordisk's products, including Victoza, were included on OptumRx's formularies and increasing OptumRx's profits by fraudulently and artificially increasing the list price of Victoza at the expense of Plaintiff and the Class, and through which the OptumRx RICO Defendants conducted a pattern of racketeering activity under 18 U.S.C. § 1961(4).
- 120. Alternatively, each of the OptumRx RICO Defendants constitutes a single legal entity "enterprise" within the meaning of 18 U.S.C. § 1961(4), through which the OptumRx RICO Defendants conducted a pattern of racketeering activity. The OptumRx RICO Defendants' separate legal statuses facilitated the fraudulent scheme and provided a hoped-for shield from liability for the OptumRx RICO Defendants and their coconspirators. The enterprises, alleged in this and the previous paragraph, are referred to collectively as the "OptumRx RICO Enterprise."
- 121. At all relevant times, the OptumRx RICO Enterprise constituted a single "enterprise" or multiple enterprises within the meaning of 18 U.S.C. § 1961(4), as legal entities, as well as individuals and legal entities associated-in-fact for the common purpose of engaging in the OptumRx RICO Defendants' profit-making scheme.
- 122. The association-in-fact OptumRx RICO Enterprise consisted of the following entities and individuals: (a) OptumRx, its subsidiaries, executives, employees, and agents; and (b) Novo Nordisk, its subsidiaries, executives, employees, and agents.

- 123. While each of the OptumRx RICO Defendants acquired, maintained control of, were associated with, and conducted or participated in the conduct of the OptumRx RICO Enterprise's affairs, at all relevant times, the OptumRx RICO Enterprise: (a) had an existence separate and distinct from each OptumRx RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the OptumRx RICO Defendants engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the OptumRx RICO Defendants, along with other individuals and entities, including unknown third parties.
- 124. The OptumRx RICO Defendants and their co-conspirators, through their illegal OptumRx RICO Enterprise, engaged in a pattern of racketeering activity, which involved a fraudulent scheme to increase revenue for the OptumRx RICO Defendants and the other entities and individuals associated-in-fact with the OptumRx RICO Enterprise's activities by selling Victoza at an inflated and artificial price ("the OptumRx RICO Scheme").
- 125. The OptumRx RICO Defendants orchestrated the OptumRx RICO Scheme, whereby OptumRx, as a PBM, leveraged its dominate position in the insurance market to demand that manufacturers, like Novo Nordisk, pay substantial kickbacks in order to have their products included or be given priority on OptumRx's formularies.
- 126. Novo Nordisk facilitated the OptumRx RICO Scheme by agreeing to provide ever-larger "discounts" or "rebates" to OptumRx in order to gain or maintain access to its formularies and funding those discounts by artificially increasing the list price of Victoza.

127. In furtherance of the scheme, the OptumRx RICO Defendants each affirmatively misrepresented or concealed the existence of the inflated and fraudulent nature of these list price increases as well as the existence, amount, and purpose of the discounts given to OptumRx to Plaintiff, the Class, consumers, health care payers, and the general public. Specifically, the OptumRx RICO Defendants claimed that the rebates paid to OptumRx were for the purpose of lowering costs when, in fact, they were *quid pro quo* payments for formulary access that had the opposite effect for Plaintiff and the members of the Class.

B. The OptumRx RICO Enterprise Sought to Fraudulently Increase Defendants' Profits and Revenues.

- 128. Each OptumRx RICO Defendant benefited financially from the OptumRx RICO Enterprise. OptumRx received direct rebate payments from Novo Nordisk, a large portion of which it pocketed as pure profit, as well as other fees.
- 129. In exchange, Novo Nordisk's products received a favorable position on one, or a number of OptumRx's formularies, translating into higher sales and profits. And because Novo Nordisk financed the payment of rebates by inflating the list prices for Victoza, they maintained and, in some cases, increased their profit margins.
- 130. At all relevant times, the OptumRx RICO Enterprise: (a) had an existence separate and distinct from each OptumRx RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the OptumRx RICO Defendants engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the OptumRx RICO Defendants, along with other individuals and entities, including unknown third parties that operated an association-in-fact enterprise, which was formed for the purpose of ensuring that Novo Nordisk's products, including Victoza, were

included on OptumRx's formularies and increasing OptumRx's profits by fraudulently

and artificially increasing the list price of Victoza at the expense of Plaintiff and the

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Class, and paying rebates from the inflated list price. 131. The OptumRx RICO Defendants and their co-conspirators, through their illegal Enterprise, engaged in a pattern of racketeering activity, which involved a fraudulent scheme to increase revenue for the OptumRx RICO Defendants and the other entities and individuals associated-in-fact with the Enterprise's activities through the

illegal scheme to sell Victoza at an inflated and artificial price.

The OptumRx RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, such as the marketing, promotion, advertisement, distribution, and sale of Victoza throughout the country, and the receipt of monies from the sale of the same.

- 133. Within the OptumRx RICO Enterprise, there was a common communication network by which co-conspirators shared information on a regular basis. The OptumRx RICO Enterprise used this common communication network for purposes of marketing, pricing, and engaging in negotiations regarding Victoza, its pricing, and placement or position on OptumRx's formularies and for furthering the OptumRx RICO Scheme.
- 134. Each participant in the OptumRx RICO Enterprise had systematic linkages to each other through corporate ties, contractual relationships, financial ties, and a continuing coordination of activities. Through the OptumRx RICO Enterprise, the OptumRx RICO Defendants functioned as a continuing unit with the purpose of furthering the OptumRx RICO Scheme.

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- 135. The OptumRx RICO Defendants participated in the operation and management of the OptumRx RICO Enterprise by directing its affairs, as described herein. While the OptumRx RICO Defendants participated in, and are members of, the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.
- 136. The OptumRx RICO Defendants exerted substantial control over the OptumRx RICO Enterprise, and participated in the affairs of the enterprise by: (a) negotiating and/or offering discounts for Victoza; (b) misrepresenting and/or concealing the existence, amount, or purpose of the discounts negotiated for Victoza; (c) misrepresenting and/or concealing the effect that the negotiated discounts had on the price of Victoza; (d) negotiating and/or setting the list price for Victoza; (e) misrepresenting and/or concealing the true cost of Victoza; (f) publishing, reproducing, and/or distributing documents containing the list price for Victoza; (g) negotiating and/or offering preferred formulary placement for Victoza; (h) misrepresenting and/or concealing the true nature of the relationship and agreements between the members of the enterprise and its effect on the pricing of Victoza; (i) otherwise misrepresenting and/or concealing the inflated and fraudulent nature of the pricing of Victoza; (j) collecting discounts, revenues, and/or profits from the sale of Victoza; and (k) ensuring that the other OptumRx RICO Defendants and unnamed co-conspirators complied with and concealed the fraudulent scheme.
- 137. Without each OptumRx RICO Defendant's willing participation, the OptumRx RICO Scheme and common course of conduct would not have been successful.

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138. The OptumRx RICO Defendants directed and controlled the ongoing organization necessary to implement the scheme at meetings and through communications of which Plaintiff cannot fully know at present, because such information lies in the Defendants' and others' hands.

C. Predicate Acts: Mail and Wire Fraud.

- 139. To carry out, or attempt to carry out, the scheme to defraud, the OptumRx RICO Defendants, each of whom is a person associated-in-fact with the OptumRx RICO Enterprise, did knowingly conduct or participate, directly or indirectly, in the affairs of the OptumRx RICO Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).
- 140. Specifically, the OptumRx RICO Defendants have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.
- 141. The multiple acts of racketeering activity which the OptumRx RICO Defendants committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the OptumRx RICO Defendants' regular use of the facilities, services, distribution channels, and employees of the OptumRx RICO Enterprise. The OptumRx RICO Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

- 142. The OptumRx RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions.
- 143. In devising and executing the illegal scheme, the OptumRx RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiff and the Class or to obtain money from Plaintiff and the Class by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the OptumRx RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.
- 144. The OptumRx RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:
 - (a) <u>Mail Fraud</u>: The OptumRx RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, price, and/or sell Victoza by means of false pretenses, misrepresentations, promises, and omissions.
 - (b) <u>Wire Fraud</u>: The OptumRx RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises, and omissions.

- 145. The OptumRx RICO Defendants' use of the mails and wires include, but are not limited to: (a) the transmission of marketing or other materials indicating, setting, or negotiating the price of Victoza; (b) the transmission of marketing or other materials indicating or advertising that any of the OptumRx RICO Defendants reduce the price of Victoza; (c) written, telephone, or electronic communications regarding and/or negotiating the price of Victoza; (d) written, telephone, or electronic communications regarding and/or negotiating discounts and/or rebates for Victoza; (e) written, telephone, or electronic communications regarding the existence, amount, or purpose of discounts and/or rebates for Victoza; (f) the transmission and/or distribution of Victoza through the mails; and (g) the use of the mails or wires to bill for or collect discounts, revenues, and/or profits from the sale of Victoza.
- 146. The OptumRx RICO Defendants also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail with various other affiliates, regional offices, divisions, dealerships, and other third-party entities in furtherance of the scheme.
- 147. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct designed to increase the cost of Victoza and fraudulently extract hundreds of millions of dollars of revenue from Plaintiff and the Class.
- 148. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of predicate acts of mail and/or wire fraud. They include thousands of communications to

- perpetuate and maintain the scheme, including the things and documents described above.
- described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the OptumRx RICO Defendants conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with the OptumRx RICO Defendants in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenues, increase market share, and/or minimize losses for the Defendants and their unnamed co-conspirators throughout the illegal scheme and common course of conduct.
- 150. The OptumRx RICO Defendants aided and abetted others in the violations of the above laws.
- 151. To achieve their common goals, the OptumRx RICO Defendants hid from Plaintiff, the Class, insurers, health plans, and the general public the true net price of Victoza, the inflated and fraudulent nature of the list price of Victoza, the relationship between the OptumRx RICO Defendants and their impact upon the price of Victoza, and the existence, amount, and purpose of rebates and discounts given for Victoza, and the portion of the rebates and discounts pocketed by OptumRx.
- 152. The OptumRx RICO Defendants and each member of the conspiracy, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the

OptumRx RICO Defendants and their co-conspirators had to agree to conceal their fraudulent negotiations and pricing tactics.

- 153. The OptumRx RICO Defendants knew, and intended that, Plaintiff and Class members would rely on the material misrepresentations and omissions made by them and incur increased costs as a result. Indeed, if Plaintiff and the Class did not make inflated payments for Victoza, the OptumRx RICO scheme could not succeed.
- 154. As described herein, the OptumRx RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiff and the Class based on their misrepresentations and omissions, while providing Victoza that was worth significantly less than the purchase price paid. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.
- 155. During the OptumRx RICO Defendants' determination of discounts and/or rebates for Victoza, the true purpose of the discounts, the true cost of Victoza, and the inflated and fraudulent nature of their pricing was revealed to each of the OptumRx RICO Defendants. Nevertheless, the OptumRx RICO Defendants continued to disseminate misrepresentations regarding the true cost of Victoza as well as the existence, amount, and purpose of the discounts on those products, in furtherance of the scheme.
- 156. By reason of, and as a result of the conduct of the OptumRx RICO Defendants, and in particular, their pattern of racketeering activity, Plaintiff and the Class have been injured in their business and/or property in multiple ways, including but not limited to paying excessive and inflated prices for Victoza.

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157. The OptumRx RICO Defendants' violations of 18 U.S.C. §1962(c) and (d) have directly and proximately caused injuries and damages to Plaintiff and the Class who are entitled to bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

COUNT TWO — VIOLATION OF THE CALIFORNIA LEGAL REMEDIES ACT (CAL. CIV. CODE § 1750, ET SEQ.)

(By Plaintiff on Behalf of All Members of the Class except those in ERISA Plans, **Against Defendant OptumRx**)

- 158. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this complaint.
- 159. Plaintiff brings this Count individually and on behalf of the Class against Defendant OptumRx.
- 160. The California Legal Remedies Act ("CLRA") prohibits "unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer[.]" Cal. Civ. Code § 1770(a).
 - 161. Each Defendant is a "person" under Cal. Civ. Code § 1761(c).
- 162. Plaintiff and Class members are "consumers" as defined by Cal. Civ. Code § 1761(d), who purchased Victoza.
- 163. Defendants thus violated the CLRA, at a minimum by: (1) making misleading statements regarding the true cost of the price of Victoza or causing reasonable inferences about the cost that had the tendency to mislead consumers, including but not limited to publishing, setting, or distributing the list price of Victoza;

- (2) engaging in advertising concerning the role that Defendants played in setting the price paid for Victoza, including but not limited to marketing material averring that OptumRx make efforts to decrease the price of prescription drugs and/or Victoza for consumers; (3) failing to disclose the inflated and/or fraudulent nature of the list price(s) set and/or charged by Novo Nordisk for Victoza; (4) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Novo Nordisk to OptumRx and/or negotiated by OptumRx in exchange for inclusion and/or tier placement of Novo Nordisk's products, including Victoza, on OptumRx's formularies; (5) making material misrepresentations regarding or failing to disclose the portion of discounts, rebates, and/or other payments from by Novo Nordisk that OptumRx keeps as profit; and/or (6) engaging in misleading, false, unfair and/or deceptive acts or practices by selling and/or facilitating the sale Victoza at a grossly inflated and/or fraudulently obtained price point.
- 164. The foregoing violations caused harm to Plaintiff and the members of the Class, and are likely to harm consumers in the future if Defendants' practices are not stopped.
 - 165. Plaintiff seeks injunctive relief under the CLRA.
- 166. Plaintiff also seeks, under Cal. Civ. Code § 1780(a), monetary relief against Defendants.
- 167. Under Cal. Civ. Code § 1780(b), Plaintiff seek an additional award against each Defendant of up to \$5,000 for each Plaintiff or Class member who qualifies as a "senior citizen" or "disabled person" under the CLRA. Each Defendant knew or should have known that its conduct was directed to one or more Plaintiff or Class members who

are senior citizens or disabled persons. Defendants' conduct caused one or more of these senior citizens or disabled persons to suffer a substantial loss of property set aside for retirement or for personal or family care and maintenance, or assets essential to the health or welfare of the senior citizen or disabled person. One or more Plaintiff or Class members who are senior citizens or disabled persons are substantially more vulnerable to each Defendant's conduct because of age, poor health or infirmity, impaired understanding, restricted mobility, or disability, and each of them suffered substantial physical, emotional, or economic damage resulting from each Defendant's conduct.

- 168. Plaintiff further seeks an order enjoining Defendants' unfair or deceptive acts or practices, restitution, costs of court, and attorneys' fees pursuant to Cal. Civ. Code § 1780(e), and any other just and proper relief available under the CLRA.
- 169. Plaintiff sent letters complying with Cal. Civ. Code § 1780(b) to Defendants concurrently with the filing of this Complaint. This Count is a placeholder only and will be formally asserted 30 days after demand letters were sent if Defendants fail to remedy their unlawful conduct.

COUNT THREE — VIOLATION OF THE CALIFORNIA UNFAIR COMPETITION LAW (CAL. BUS. & PROF. CODE § 17200, ET SEQ.)

(By Plaintiff on Behalf of All Members of the Class except those in ERISA Plans, Against Defendant OptumRx)

- 170. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this complaint.
- 171. Plaintiff brings this Count individually and on behalf of the Class against Defendant OptumRx.

- 172. California Business and Professions Code § 17200 (the "Unfair Competition Law," or "UCL") prohibits "unlawful, unfair, or fraudulent business acts or practices." Defendants violated the "unlawful" prong of § 17200 by, *inter alia*, their violations of the CLRA, Cal. Civ. Code § 1750, *et seq.*, Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962, *et seq.* as described above. Defendants also violated the "fraudulent" prong of § 17200 through their pricing fraud, as described throughout this complaint. And Defendants violated the "unfair" prong of § 17200 because the acts and practices set forth in this complaint, including artificially inflating list prices to offer large rebates to PBMs caused Defendants to profit at the expense of consumers, and the harm caused to consumers greatly outweighs any benefits associated with those practices.
- 173. Defendants' actions, as set forth above, occurred within the conduct of their business, and in trade or commerce.
- 174. Plaintiff requests that this Court enter such orders or judgments as may be necessary, including a declaratory judgment that each Defendant has violated the UCL; an order enjoining Defendants from continuing their unfair, unlawful and/or fraudulent trade practices; an order restoring to Plaintiff any money lost as result of each Defendant's unfair, unlawful, and/or fraudulent trade practices, including restitution and disgorgement of any profits Defendants received as a result of their unfair, unlawful, or fraudulent practices, as provided in Cal. Bus. & Prof. Code § 17203, Cal. Civ. Proc. Code § 384, and Cal. Civ. Code § 3345; and for any other relief as may be just and proper.

COUNT FOUR — VIOLATION OF THE MICHIGAN CONSUMER PROTECTION ACT (MICH. COMP. LAWS § 445.903, ET SEQ.)

(By Plaintiff on Behalf of All Michigan Members of the Class except those in ERISA Plans, Against Defendants OptumRx and Novo Nordisk)

- 175. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this complaint.
- 176. Plaintiff brings this Count individually and on behalf of the members of the Class who reside in Michigan against Defendants OptumRx and Novo Nordisk.
- 177. The Michigan Consumer Protection Act ("Michigan CPA") prohibits "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce," including "[m]aking false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;" "[f]ailing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer;" "charging the consumer a price that is grossly in excess of the price at which similar property or services are sold;" "[m]aking a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is;" or "[f]ailing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner." Mich. Comp. Laws § 445.903(1).
- 178. Plaintiff and Class members are "person[s]" within the meaning of the Mich. Comp. Laws § 445.902(1)(d).
- 179. Each Defendant is a "person" engaged in "trade or commerce" within the meaning of the Mich. Comp. Laws § 445.902(1)(d) and (g).

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- 180. Defendants thus violated the Michigan CPA, at a minimum by (1) making misleading statements regarding the true cost of the price of Victoza or causing reasonable inferences about the cost that had the tendency to mislead consumers, including but not limited to publishing, setting, or distributing the list price of Victoza; (2) engaging in advertising concerning the role that Defendants played in setting the price paid for Victoza, including but not limited to marketing material averring that OptumRx make efforts to decrease the price of prescription drugs and/or Victoza for consumers; (3) failing to disclose the inflated and/or fraudulent nature of the list price(s) set and/or charged by Novo Nordisk for Victoza; (4) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Novo Nordisk to OptumRx and/or negotiated by OptumRx in exchange for inclusion and/or tier placement of Novo Nordisk's products, including Victoza, on OptumRx's formularies; (5) making material misrepresentations regarding or failing to disclose the portion of discounts, rebates, and/or other payments from by Novo Nordisk that OptumRx keeps as profit; and/or (6) engaging in misleading, false, unfair and/or deceptive acts or practices by selling and/or facilitating the sale Victoza at a grossly inflated and/or fraudulently obtained price point.
- 181. The foregoing violations caused harm to Plaintiff and the members of the Class, and are likely to harm consumers in the future if Defendants' practices are not stopped.
- 182. Plaintiff seeks injunctive relief to enjoin Defendants from continuing their unfair and deceptive acts; monetary relief against each Defendant measured as the greater of (a) actual damages in an amount to be determined at trial; (b) statutory damages in the

amount of \$250 for each plaintiff; (c) reasonable attorneys' fees; and (d) any other just and proper relief available under Mich. Comp. Laws § 445.911.

183. Plaintiff also seek punitive damages because each Defendant carried out despicable conduct with willful and conscious disregard of the rights and safety of others. Defendants maliciously and egregiously misrepresented actual net price of Victoza, inflated the list prices of Victoza, and concealed the reasons for, and amount of, the rebates offered to PBMs in order to increase their profits at the expense of consumers. Defendants manipulated the price of their life-saving products without regard to the impact of their scheme on consumers. Defendants' conduct constitutes malice, oppression, and fraud warranting punitive damages.

COUNT FIVE — VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT (N.J. STAT. ANN. § 56:8-1, ET SEQ.)

(By Plaintiff on Behalf of All Members of the Class except those in ERISA Plans, Against Defendant Novo Nordisk)

- 184. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this complaint.
- 185. Plaintiff brings this Count individually and on behalf of the Class against Defendant Novo Nordisk.
- 186. The New Jersey Consumer Fraud Act ("New Jersey CFA") makes unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or

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⁷⁹ N.J. Stat. Ann. § 56:8-2.

advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby "79

- 187. Defendants, Plaintiff, and the Class are "persons" within the meaning of N.J. Stat. Ann. § 56:8-1(d).
- 188. Defendants engaged in "sales" of "merchandise" within the meaning of N.J. Stat. Ann. § 56:8-1(c), (d).
- 189. Defendants thus violated the New Jersey CFA, at a minimum by: (1) making misleading statements regarding the true cost of the price of Victoza or causing reasonable inferences about the cost that had the tendency to mislead consumers, including but not limited to publishing, setting, or distributing the list price of Victoza; (2) engaging in advertising concerning the role that Defendants played in setting the price paid for Victoza, including but not limited to marketing material averring that OptumRx make efforts to decrease the price of prescription drugs and/or Victoza for consumers; (3) failing to disclose the inflated and/or fraudulent nature of the list price(s) set and/or charged by Novo Nordisk for Victoza; (4) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Novo Nordisk to OptumRx and/or negotiated by OptumRx in exchange for inclusion and/or tier placement of Novo Nordisk's products, including Victoza, on OptumRx's formularies; (5) making material misrepresentations regarding or failing to disclose the portion of discounts, rebates, and/or other payments from by Novo Nordisk that OptumRx keeps as profit; and/or (6) engaging in misleading,

false, unfair and/or deceptive acts or practices by selling and/or facilitating the sale Victoza at a grossly inflated and/or fraudulently obtained price point.

- 190. The foregoing violations caused harm to Plaintiff and the members of the Class, and are likely to harm consumers in the future if Defendants' practices are not stopped.
- 191. Plaintiff is entitled to recover legal and/or equitable relief, including an order enjoining Defendants' unlawful conduct; treble damages; costs; and reasonable attorneys' fees pursuant to N.J. Stat. Ann. § 56:8-19; and any other just and appropriate relief.

COUNT SIX — COMMON LAW FRAUD

(By Plaintiff on Behalf of All Members of the Class except those in ERISA Plans, Against Defendants OptumRx and Novo Nordisk)

- 192. Plaintiff incorporates by reference each preceding paragraph as though fully set forth herein.
- 193. Plaintiff brings this Count individually and on behalf of the Class except those in ERISA plans against Defendants OptumRx and Novo Nordisk.
- 194. As alleged extensively above, Defendants affirmatively misrepresented and/or concealed and suppressed material facts concerning: (a) the true cost and/or price of Victoza; (b) the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for Victoza; (c) the existence, amount, and/or purpose(s) of discounts and/or rebates offered and/or negotiated by Defendants for Victoza; and (d) the role that Defendants' played in the price paid for Victoza, including but not limited to marketing material averring that Defendants decrease the price of prescription drugs and/or Victoza for consumers.

- 195. Defendants valued their profits over the trust, health and safety of Plaintiff and other Class members.
- 196. Necessarily, Defendants took steps to ensure that their employees and coconspirators did not reveal the details of their scheme to inflate the price of Victoza to consumers, including Plaintiff and Class members.
- 197. Defendants' false representations and omissions were material to consumers, Plaintiff and the members of the Class.
- 198. Plaintiff and Class members reasonably relied on Defendants' deception, and Defendants intended that they would so rely. Plaintiff and Class members had no way of discerning that Defendants were, in fact, deceiving them because they possessed exclusive knowledge regarding the nature of Victoza's pricing; intentionally concealed the foregoing from, Plaintiff, the Class and the public; and made incomplete or negligent representations about the pricing of Victoza and the Defendants' role in that pricing, while purposefully withholding material facts from Plaintiff and the Class that contradicted these representations.
- 199. Defendants' actions, representations, and misrepresentations demonstrate callous disregard for not only the rule of law but also public health. Indeed, as a direct result of Defendants' actions, access to life-saving medication has been limited, denied, or forgone.
- 200. Defendants owed Plaintiff and the Class a duty to disclose, truthfully, all the facts concerning the true cost of Victoza and the inflated and fraudulent nature of their pricing; the existence, amount, and purpose of rebated and discounts negotiated for those products; and the role that Defendants played in increasing the price of Victoza.

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- 201. Defendants hatched their deceptive schemes and knew that their customers, including Plaintiff and Class members, did not know about (and could not reasonably discover) the manner in which they sought to artificially inflate the price of Victoza. Defendants not only concealed all the facts concerning the true cost of Victoza, but went further to make affirmative misrepresentations in marketing materials and other communications, that Defendants worked to lower the ultimate cost of prescription medications like Victoza. Defendants engaged in this fraudulent concealment at the expense of Plaintiff and the Class.
- 202. Plaintiff and the Class members were not aware of the concealed and misrepresented material facts referenced above, and they would not have acted as they did, had they known the truth.
- 203. As a direct and proximate result of Defendants' fraudulent scheme, Plaintiff and the Class members sustained damages, including but not limited to paying excessive and inflated prices for Victoza.
- 204. Defendants are liable to Plaintiff and the Class members for damages in an amount to be proven at trial. Moreover, because Defendants acted wantonly, maliciously, oppressively, recklessly, deliberately, and with intent to defraud Plaintiff and Class members for the purpose of enriching themselves at Plaintiff's and the Class members' detriment, Defendants' conduct warrants substantial punitive and exemplary damages in an amount to be determined at trial.

COUNT SEVEN — UNJUST ENRICHMENT

(By Plaintiff on Behalf of All Members of the Class except those in ERISA Plans, Against Defendants OptumRx and Novo Nordisk)

- 205. Plaintiff incorporates by reference each preceding paragraph as though fully set forth herein.
- 206. Plaintiff brings this Count on behalf of themselves and all members of the Class except those in ERISA plans against Defendants OptumRx and Novo Nordisk.
- 207. Defendants have benefitted from selling, setting prices for and negotiating discounts for Victoza marketed and sold at an artificially inflated price.
- 208. Defendants have received and retained unjust benefits from the Plaintiff and Class members, in the form of costs paid, copayments, and coinsurance payments, and inequity has resulted.
 - 209. It is inequitable and unconscionable for Defendants to retain these benefits.
- 210. Because Defendants concealed their fraud and deception, Plaintiff and the Class members were not aware of the true facts concerning Defendants efforts to inflate the cost of Victoza described herein and did not benefit from Defendants' misconduct.
 - 211. Defendants knowingly accepted the unjust benefits of its fraudulent conduct.
- 212. As a result of Defendants' misconduct, the amount of their unjust enrichment should be disgorged and returned to Plaintiff and Class members, in an amount to be proven at trial.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), (b)(2), and/or (b)(1), and direct that

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27 28 be given to the Class, and declare Plaintiff as the representative of the Class, and appoint her attorneys as Class Counsel; Enter judgments against Defendants and in favor of Plaintiff and the Class В.

reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2),

- for violations of the federal and state laws and legal standards invoked in this Complaint;
- C. Award preliminary and permanent injunctive and other equitable relief as is necessary to protect the interests of Plaintiff and the Class, including, *inter alia*, an order prohibiting Defendants from engaging in the unlawful acts described above; an order requiring Defendants or their agents to disclose the existence and/or amount of any rebates, discounts, fees, or other payments received by the PBM Defendants for including Victoza on any formulary, and an order requiring Defendants or their agents to disclose the true net price of Victoza collected by the Manufacturer Defendants;
- D. Order Defendants to pay pre-judgment and post-judgment interest as provided for by law or allowed in equity;
- E. Award Plaintiff and the Class damages (three times overcharges) in an amount to be determined at trial;
- F. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law, including under RICO, the common fund doctrine, and applicable state law;
 - G. Find that Defendants are jointly and severally liable for all claims;
- Η. Order that Defendants must notify each and every individual who paid a copayment or coinsurance for covered prescription products that exceeded the true cost of

Document 1

Filed 05/23/17

Case 8:17-cv-00900-DOC-KES

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Page 71 of 71 Page ID